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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 101.0042-05000

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on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/098,683	March 15, 2002

First Named Inventor: Gary Karlin Michelson

Art Unit	Examiner
3773	Melanie Ruano Tyson

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [X] attorney or agent of record. Registration number 34,383
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Thomas H. Martin
Typed or printed name

330-877-0700
Telephone number

May 29, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[X] *Total of 1 forms are submitted.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 3733

PATENT
Attorney Docket No. 101.0042-05000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Confirmation No.: 7210
Gary Karlin Michelson	)	
Serial No.: 10/098,683	)	Group Art Unit: 3773
Filed: March 15, 2002	)	Examiner: Melanie Ruano Tyson
For: SPINAL IMPLANT CONTAINING MULTIPLE BONE GROWTH PROMOTING MATERIALS (as amended)	)	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In reply to the Final Office Action of March 14, 2008, Applicant submits the following remarks for consideration by the Members of the pre-appeal brief conference.

I. Brief Background

The application includes two independent claims, claims 54 and 79, generally drawn to an apparatus comprising an interbody spinal fusion implant in combination with liquid and solid fusion promoting materials (independent claim 54) or with bioactive and bioresorbable materials (independent claim 79) provided in at least a portion of the hollow interior of the implant. The following issues are the subject of this Request for a Pre-Appeal Conference: (1) the rejection of independent claim 54 under 35 U.S.C. § 112, first paragraph; (2) the objection to the Abstract under 35 U.S.C. § 132(a); and (3) the rejection of independent claims 54 and 79 under 35 U.S.C. § 103(a).

II. Clear Errors

(1) The Examiner's rejection of claims 54-65, 67-78, and 104-106 (including independent claim 54) under 35 U.S.C. § 112, first paragraph, as having new matter is erroneous because:

(a) according to the Examiner, "Applicant failed to disclose a liquid fusion promoting material and a solid fusion promoting material at the time the application was filed (see claims 54, 67, and 104-106)", and "simply disclosed bone fusion promoting material, such as hydroxyapatite, tricalcium phosphate, and bone morphogenetic protein" (Office Action of March 14, 2008, paragraph bridging pages 2 and 3);

(b) in response to Applicant's arguments, the Examiner indicated that "the terms 'liquid' and 'solid' cover other materials in addition to those disclosed by the applicant," and "although the materials disclosed by the applicant may inherently contain these properties, the applicant did not disclose all liquid and solid fusion promoting materials" (Office Action of March 14, 2008, second full paragraph on page 5);

(c) the Examiner reasons that "the limitations 'liquid fusion promoting material' and 'solid fusion promoting material' may include all other liquid and solid fusion promoting materials other than those disclosed by the applicant at the time the invention was filed," and, "therefore, the claims contain new matter and the rejection stands" (Advisory Action of May 23, 2008);

(d) in response, Applicant submits that the Examiner's rejection does not align with the application of 35 U.S.C. § 112, first paragraph, as discussed in the MPEP;

(i) MPEP § 2163 II.A.3(b) indicates that claim limitations can be "inherently supported in the originally filed disclosure" to comply with the written description requirement of 35 U.S.C. § 112, first paragraph, and, citing Hyatt v. Boone, 146 F.3d 1348 (Fed. Cir. 1998), indicates that "where an explicit limitation in a claim 'is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation'";

(e) both hydroxyapatite and tricalcium phosphate are generally used in solid form as fusion promoting materials, and BMP is generally used in liquid form as a fusion promoting material, and, in the case of the implant coatings referenced in Applicant's specification, Applicant submits that, as used to promote bone fusion, the solid states of hydroxyapatite and hydroxyapatite tricalcium phosphate, and the liquid state of BMP are inherent, not probable or possible, properties of those materials;

(f) given the inherent properties of hydroxyapatite, hydroxyapatite tricalcium phosphate, and BMP, Applicant submits that no new matter has been introduced in the claims;

(g) furthermore, because a person of ordinary skill in the art at the time the patent application was filed would have understood that Applicant disclosed solid and liquid fusion promoting materials, Applicant submits that the Examiner has not made a prima facie case for the rejection under 35 U.S.C. § 112, first paragraph; and

(h) therefore, the Examiner's rejection of claims 54, 67, and 104-106 under 35 U.S.C. § 112, first paragraph, has been overcome.

(2) The Examiner's objection under 35 U.S.C. § 132(a) as introducing new matter to the Abstract is erroneous because:

(a) given that claims 54, 67, and 104-106 are patentable over the Examiner's rejection under 35 U.S.C. § 112, first paragraph, Applicant submits that the Abstract is adequately supported by the original disclosure; and

(b) therefore, no new matter has been introduced in the amendments to the Abstract, and the Examiner's objection to the Abstract under 35 U.S.C. § 132(a) is now moot.

(3) The Examiner's rejection under of claims 54-65, 67-90, and 92-108 (including independent claims 54 and 79) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,026,373 to Ray et al. ("Ray") is erroneous because:

(a) the Examiner indicates that "it would have been obvious to one having

ordinary skill in the art at the time the invention was made to employ the bone growth promoting materials as claimed in Ray's implant in order to promote new bone growth, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice";

(b) independent claim 54 recites an apparatus comprising an interbody spinal fusion implant, and a liquid fusion promoting material and a solid fusion promoting material provided in the hollow interior of the implant, and independent claim 79 recites an apparatus comprising an interbody spinal fusion implant, and a bioactive material and a bioresorbable material provided in the hollow interior of the implant;

(c) besides making an assertion that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the bone growth promoting materials as claimed in Ray's implant in order to promote new bone growth," the Examiner has not pointed to any teaching or suggestion in the prior art affording such an assertion;

(d) more specifically, the Examiner has not pointed to any teaching or suggestion in the prior art for liquid and solid fusion materials provided in the hollow interior of the interbody spinal fusion implant and for bioactive and bioresorbable materials provided in the hollow interior of the interbody spinal fusion implant as recited in independent claims 54 and 79, respectively; and

(e) accordingly, Applicant submits that independent claims 54 and 79 are not obvious in view of the Examiner's rejection under 35 U.S.C. § 103(a) based on Ray.

III. Conclusion

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Members of the Pre-Appeal Brief Conference reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: May 29, 2008

By: _____
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